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Innovation Policy, Academia and Intellectual Property

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INNOVATION POLICY, ACADEMIA AND INTELLECTUAL PROPERTY RIGHTS

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The Author explores the current debate on the role of universities in innovation policy and in claiming intellectual property rights (IPR), especially patents, for results of research. The increased importance of IP and the wealth creation that takes place in an intellectual value creating process – from the definition of an innovation to the claiming of IPR for it, to the managing of IPR, including evaluating its financial value and exploiting it on the financial markets – have brought about significant legislative changes in several European countries.

This paper argues that these changes require an internal policy within universities that emphasize the role and responsibilities of researchers and universities in managing IP. They also require an adaptation of the existing IP regulatory system for this new environment. An example of such a need is the reformulation and clarification of the so-called "research exemption" in patent law. This paper deals mainly with the European situation, but presents some comparative aspects and emphasizes that solutions preferably should be found on an international, global level.

INTRODUCTION

There is wide common understanding that the university-industry technology transfer forms an important – today even crucial – part of national innovation systems. There is also a growing awareness that academia can and should play a more efficient role in facilitating IP claims of research and in creating favorable opportunities for commercialization of research results. There have been several

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international reports from the Organisation for Economic Co-operation and Development (OECD) stating that the potential for commercialization of research done within universities is not fully utilized.[2]

An important element of the infrastructure for national innovation policy is IPR legislation. Traditionally this legislation has been regarded both as a provider of incentives for the generation of new knowledge and as a tool for spreading knowledge or disseminating new technology. Furthermore, the IPR regime has not been regarded as a direct tool or instrument for innovation policy, but more as a provider of a stable infrastructure and precondition for that policy. In this regard, there are several reasons for reconsidering these traditional roles of IPR legislation.[3] One of the many reasons for reconsidering some of the IP regulation is due to the changed role of academia in claiming IP for its research results and managing the commercialization of this IP.

The process of change regarding the role and tasks of academia in claiming IP has been profound in Europe. This paper notes the integration, especially in Europe, of universities into national innovation systems. Structural and legislative changes have been undertaken and, as a result, universities are expected to play an active role in the promotion and commercialization of research results. The aim of this article is to map this development by presenting the Finnish case as an example of the more general Nordic development. Secondly, I want to identify and discuss some of the

2. *See* ORG. FOR ECON. CO-OPERATION & DEV., TURNING SCIENCE INTO BUSINESS (2003) [hereinafter SCIENCE INTO BUSINESS]; ORG. FOR ECON. CO-OPERATION & DEV., SCIENCE, TECHNOLOGY AND INDUSTRY SCOREBOARD 2005—TOWARDS A KNOWLEDGE-BASED ECONOMY (2005).

3. Several international reports published lately stress the importance of IPR legal regimes as instruments for innovation policy. *See e.g.*, Eric J. Iversen, *Fundamental and Contextual Issues Involving the Strategic Use of IPRs* (Center for Innovative Research (STEP), Working Paper No. A-01, 2002), *available at* http://www.step.no/Notater/A-01-2002.pdf; Robin Cowan, Luc Soete & Chervonnaya Tchervonnava, *Knowledge Transfer and the Services Sector in the Context of the New Economy* (Maastricht Merit-Institute, Research Memoranda 020, 2002), *available at* http://www.merit.unu.edu/publications/wppdf//wp-.pdf; PATENTS IN THE KNOWLEDGE-BASED ECONOMY (Wesley M. Cohen & Stephen A. Merrill, Eds., 2003); *see also* SCIENCE INTO BUSINESS, *supra* note 2.

problems present IP regulation, especially patent law, poses for this development. My perspective is in that sense contrary to the common point of view, which focuses on the principles of academic research and assumes IP to be a stable factor. That discussion then questions to what extent these principles have to be reshaped or are currently undermined as a consequence of new university policies. My question is the opposite: to what extent can the present IP regime be regarded to be designed to meet the challenges created by the new roles of universities?

I. THE RELATIONSHIP BETWEEN ACADEMIA AND BUSINESS

Historically, the relationship between industry and academia has differed considerably by the times. We can distinguish three different models:[4]

A. The Ivory Tower or Open Research Model

This model regards academia as the right place for basic research while applied research with IP potential should be done within research and development (R&D) and business research. The classic Humboldt University was largely built on such ideals. Some of the principles of this model are still much respected as idealtypes, although the divide between basic research and applied research in its traditional sense seems to be obsolete.[5]

B. The Unregulated Collaboration Model

The Unregulated Collaboration Model represents a typical post-war Nordic/German approach. In this model, technology transfer

4. The elaboration of this model categorization has been made in an international project lead by Mats Lundquist and Ulf Petrusson, CIP (Gothenburg, Sweden), the results of which will be elaborated in a publication that is still in progress. The author is a part of this group and a co-author of the coming publication.

5. *See* DAVID MOWERY, RICHARD NELSON, BHAVEN SAMPAT & ARVIDS ZIEDENS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT 36 (2004).

takes place through collaboration between individual researchers and research groups on one hand and industry on the other. The role of the university as an institution is only that of a facilitator. Universities have not been covered by the regulation of employee inventions in the private sector, which gives the private industry employer the right to its employees' inventions and entitles the employee to economic compensation for the assignment. Rather, in these countries the so-called "teacher exemption" applies. Cooperation between industry and academy takes place through individual professors, and often it is informally based on long term mutual cooperation and trust. This is how big Swedish corporations have successfully cooperated with academia for decades. Companies like Astra, ABB, Volvo, Eriksson and many more are good examples of this, and the same can be said of Nokia in Finland. The model seems to work especially well in small homogenous countries, where flexible cooperation based on trust relations is possible.

Nordic universities have long developed their contacts with society and industry in an informal and collaborative manner in which the individual researcher is regarded as the most important part on the academic side. The legal base for this collaboration has been the so-called "teacher exemption." This legislation was introduced in the wake of the Second World War in Sweden and Denmark and gives the rights for inventions made at the university principally to the researcher. A similar solution was adopted by Finland and Norway as a result of the general Nordic harmonization within patent law that took place in the 1960s.[6] State universities cannot claim ownership even if the resources for the research come from public funds. This leads to a situation where the researcher primarily makes the decision to develop an invention to a commercial product, and a situation where the researcher can negotiate directly with a financier from industry, or decide to start up a spin-off company where the researcher has whole or part ownership. These arrangements have clear advantages in possibilities for free negotiation between inventors and financiers/developers, compared to

6. For information regarding this background see NIKLAS BRUUN, UPPFINNARRÄTT I ANSTÄLLNINGSFÖRHÅLLANDE 23 (1982).

other regulation systems. It also has disadvantages since there is no clearly recognized or planned "innovation system." Instead, many initiatives are made by individual researchers, who often have less knowledge and experience of developing and marketing. The risk that many innovations stemming from the university sector are ignored and forgotten because of the fairly anarchistic organization of technology transfer seems to be rather high. Thus, this chapter discusses the advantages and disadvantages for the teacher exemption, and the collaboration culture to which it often leads.

C. The Licensing Model

The Licensing Model has been applied in the United States for many years and the Bayh-Dole Act of 1980 can be described as a typical legal form of that model. Technology transfer is seen as an important task for universities, which may acquire IP and sell licenses to business. This is clearly a more formal approach than the traditional Nordic one.[7]

At present, the Nordic collaboration model is being highly debated, and a wind of regulatory change is blowing. In Denmark (1999), Germany (2002), Norway (2003), and Finland (2006) the law has been changed and the teachers' exemption abolished.[8] In Sweden a similar reform is under discussion. This means that universities are entitled to acquire rights to inventions made by faculty members. There are several reasons for this. In a global environment the traditional kind of national research structure cannot work any longer; science has to become more formal and also more professional.

7. *See* MOWERY ET AL., *supra* note 5; Michael J. Remington, *The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future*, 17 J. ASS'N U. TECH. MANAGERS 15 (2005).

8. A similar change was also made in Japan in 2004.

II. THE FINNISH EXAMPLE

A. Legislative Change: the Background

The teachers' exemption was introduced in Finland in 1967, due to a wish to synchronize laws and regulations in the Nordic sphere.[9] With the Nordic university culture in a changing world, a clash arose between traditional academic norms and the development of an entrepreneurial culture in university settings. These two cultures involve different norm systems, which also implicate laws and regulations on different levels. One is of course the teacher exemption saying that inventions belong to the inventor at the university. Another is Finnish civil servant law, which states that teachers at the university should do their official duties, i.e. teach, research, and administer activities. Another regulation system is the collective contracts between government and labor organizations which define work conditions. A third level is university administrative regulations, which state who is in charge and formally responsible for activities at the university.

B. Entrepreneurial Activities within Finnish University Culture

The following case, which shows some of the problems entailed in the transformation of a traditional Nordic university model to an entrepreneurial university, is taken from an article by Juha Tuunainen in the journal *Social Studies of Science.*[10]

A professor in bio-technology with a strong academic track record, i.e. winning competitive grants, publishing in peer-reviewed journals, and experienced in applied research, such as improving field-crop plants, was employed at Helsinki University in the early 1990s. Her research soon was supplemented by new research on insect resistance

9. A new law was introduced in 2006. For a commentary on the new legislation see NIKLAS BRUUN & MIKKO VÄLIMÄKI, IPR UNIVERSITY CENTER, KORKEAKOULUKEKSINNÖT: UUDEN LAIN TAVOITTEET, TULKINTA JA KÄYTÄNTÖÖN SOVELTAMINEN (2007).

10. *See* Juha Tuunainen, *Contesting a Hybrid Firm at a Traditional University*, 35 SOC. STUD. OF SCI. 173-210 (2004).

and development of production systems for foreign proteins in plants and improving of oat production. Her group's research program had a delicate balance between basic and applied activities, which in all was seen as a good starting point for a new company.

A firm was started that initially depended on investments and project funding from outside sources, and the professor worked 50% for the firm and the rest at her university. This arrangement, however, soon led to difficulties, since it was hard to define how much and what sort of teaching the professor should provide, according to the official rules for a teacher employed at a university. There was also a problem in how to divide and count her hours working for the startup company, since the latter was seen by the university administration as a "private interest."

There soon also was a problem with the rules of ownership. Even if the professor in the startup company stated that there were no such problems, since "Finnish law clearly said that the university researchers owned their own inventions," the university administration had the opinion that ownership must be negotiated and a contract be written. The chair at the university institution also saw himself as in charge of the activities there, and asked the professor to make a clear accounting of her activities, which the latter refused to do. The professor and the startup company were also accused of selling courses to external customers. As a result the professor was advised to apply for a permit for a "secondary occupation" or private practice, which earlier was common among university researchers involved in external affairs. This was thought to solve the problems with the boundary between the official duties for a civil servant and the private business interests in this specific case.

The firm soon relocated to the university's science park to solve some of the problems, but the move was difficult since they, to be able to continue their work, had to bring with them some material which was officially owned by the state university. The university administers were still skeptical towards the new startup firm, since, as they saw it, it was their task to ensure that the difference between public and private sector research was not blurred. As a result, the

new firm was relocated again, this time to be a part of a biotechnology research institute; the professor was soon on full leave from the university and instead working full time at the firm. Because of the risk for "conflicts of interests," the professor had to resign as a project leader at the university. The head of the institute, however, saw a problem with the firm's use of public funds and claimed that the grants received by the startup firm should not be applied for the sole benefit of the firm.

Finally, the original hybrid firm, where researchers worked both for a commercial firm and at the university, was "purified" to be a fully independent private firm and abandoned its academic activities all together. Some of the researchers who still preferred to perform academic research left the firm, and others were employed to work in fully commercial projects. The professor who started the firm later resigned her post and started to work for a large multi-national corporation.

Tuunainen points towards four basic problems with the development of entrepreneurial activities at universities in Nordic culture. In this case study there is a problem with (1) the traditional bureaucratic authority at university, (2) the teaching load between faculty members, (3) ownership of research tools and materials, and (4) the intellectual property rights of the researchers. Background in the German/Nordic university culture, where the researcher is seen as a civil servant, is quite clear, and it is also obvious that this ideal is regulated in Finnish law. The teachers' exemption, which states that the researcher has full control over the researcher's results, has also been a part of this norm system. The Finnish teachers' exemption was changed however at the beginning of 2007, and it is of interest to examine what arguments were used to argue for the change.

C. Changes to the Finnish Teachers' Exemption

In Finland, new legislation regulating rights to inventions made at higher education institutions came into force on January 1, 2007. The main features of this new legislation and the differences between

legislation adopted in different European countries are briefly dealt here.

Changes in Finnish legislation have been discussed for a long period of time, and the new legislation can be seen partly as a compromise. In principle, the new legislation maintained the teachers' exemption for traditional free research, but abolished it for contractual research and commissioned research. The consequence of this is that it will be important to draw distinctions between these categories, which might not always be easy. It is important also to mention that the changes are applied only to innovations that can be patented according to Finnish law, so the researcher's general control over research results is not changed.

The Finnish white paper which suggested the changes of the former law pointed towards the difficulties with a teachers' exemption in the new and growing research landscape.[11] The *total* external financing to universities was only 8% in 1985, but in 2002 it was 37%. The external financing for *research* was 51% in 2001, and 74% for research at professional high schools. The main part of external research financing comes from sources with a competitive application system, like the state organizations Academy of Finland, the technology council *Tekes*, and the state ministries. Private commercial companies were financing 15% of the total research at Finnish universities, a lesser part compared to the state organizations. Companies also play a minor role in financing of humanist or social sciences, but prefer to support technology and natural sciences.[12]

With a strong dependence on external financing, this new situation also resulted in larger projects and involvement of different types of personnel, some with other types of agreements on intellectual property rights. Even in the Finnish universities and high schools the teachers' exemption was not applied to all research personnel. Membership in European Union (EU) also demanded an adaptation

11. Commission White Paper on Proposed Legislation, *Regeringens proposition till Riksdagen med förslag till lag om rätt till uppfinningar som görs vid högskolor samt till lag om ändring av lagen om rätt till arbetstagares uppfinningar* 259 (2004). The new Act came into force on January 1, 2007.

12. *Id.* at 7.

to European law, since large EU projects with hundreds of different researchers in multi-national collaborations made a teachers' exemption in some countries impossible to handle. Generally, the teachers' exemption made the development of innovations to commercial use difficult to handle, and an imaginary innovation chain quite ineffective. Researchers often had difficulties finding appropriate support for the development, and, even if they did, the different ownership regulations for the members in a project group were a hindrance for successful commercialization.

When the law was set up a distinction between so called "open research" and "contract research" was made. The teachers' exemption was abolished for the latter, but kept for open research. The term contract research was used when there were more financiers than the university research councils, which normally support basic research. Open research was defined as a project where there were no other financiers involved and no agreements were attached to the use of the research results. EU projects were always to be seen as contract research, since they always involved many financiers and interests. The new law also concerned all researchers in the Finnish university sphere and also those at professional high schools.

The changes in Finnish legislation have been strongly promoted by universities and by authorities in charge of R&D policies, but the industry has been quite skeptical. One reason for the long period of discussion regarding the changes was that the industry did not applaud these changes. Some examples of clashes between university interests and industry regarding contractual terms already exist. Generally, the industry argues that it is easier to negotiate with researchers that know and understand the subject matter than with tech-transfer officers that are more interested in following general policy and in creating a surplus for the university. In some cases, large Finnish companies have announced they will not continue their cooperation with universities if the new policy is not adjusted. With this it seems that the arguments for a teachers' exemption resemble those heard in the Swedish debate. Only one country in the Nordic sphere changed its law so long ago that it is possible to do an analysis

of the outcome, and this will be discussed below with the Danish case.

D. The Content of the New Finnish Act

The Act on the Right in Inventions made at Higher Education Institutions (369/2006) came into force at the beginning of 2007. According to the Act, a university inventor must inform the employer/academic institution without delay about any invention made.

The explicit purpose of the Act is to promote the recognition, protection, and exploitation of inventions made at Finnish higher education institutions. The direct consequence of the Act will be that IPR contracts concerning patentable inventions can be made with the university's administration unit/technology transfer offices, not with individual researchers. Earlier, universities always needed a special mandate from the individual researcher in order to have the authority to agree on the rights to research results. Now they can make contractual arrangements with third parties concerning patentable inventions that may result from research projects.

If the invention is made within the framework of collaborative research (as opposed to open research/science) the university is entitled to acquire the rights to the invention within six months of its disclosure. When the university has acquired rights to the invention, the inventor will be entitled to obtain reasonable compensation for the invention. The rights to inventions resulting from open research will remain with the inventor. Such inventions, however, are subject to the duty to inform the university about the invention. The Act also contains some restrictions regarding the researcher's right to publish scientific results. The Act states that the inventor must not publish the research outcome in a manner that would jeopardize the protection or other exploitation of the invention.

The new Finnish legislation poses great challenges to universities. They will need to have some kind of patent policy in place so as to know how far to get involved in patenting and commercialization of inventions, how to make decisions on whether to acquire rights to

inventions and what to do with them, and also what kind of licensees to sell and what principles of patent licensing to adopt. It is too early to say anything about how the new regime functions. What we know from the Danish experience, however, is that a risk may exist for universities concentrating too much on showing results in numbers of patented inventions instead of in numbers of innovations that actually have lead to commercial utilization.[13]

III. TOWARDS THE ENTREPRENEURIAL UNIVERSITY

Three models were presented earlier. As has already been foreseen by several researchers, the latest developments make it plausible to see a shift towards a fourth model. They have introduced the concept of the "Entrepreneurial University," indicating that academic institutions are getting involved in the value creating process that emanates from research activities.[14]

While the legislator in Europe seems to be moving from some kind of Unregulated Collaboration Model based on free contractual relations towards a model resembling the U.S. Licensing Model, it is clear, however, that academia more and more takes on features that can be related to what has been described as the Entrepreneurial University, where the process of research, identification of innovation, claiming of IP, and managing it and its commercialization mark a complex but integrated process. The university might step in and participate in or facilitate all of this. It might even put up and finance start-up companies and spin-offs or take part in the involvement of venture capital in order to commercialize its innovations.

13. For an evaluation report in Danish see Inside Consulting, Cowi A/S & Eskil Hansen (for Videnskabsministeriet), Evaluering af forskerpatentloven [An Evaluation of the Danish Act on Researchers' Patents] (2004).

14. *See* HENRY ETZKOWITZ & LOET LYDESDORFF, UNIVERSITIES AND THE GLOBAL KNOWLEDGE ECONOMY: A TRIPLE HELIX OF UNIVERSITY-INDUSTRY-GOVERNMENT RELATIONS (1997); SCOTT ANDREW SHANE, ACADEMIC ENTREPRENEURSHIP: UNIVERSITY SPINOFFS AND WEALTH CREATION (2004).

In this context I am only interested in noting that this trend exists. The issue I want to discuss further is how the current IP regime and especially the patent regime fit into this development. In this context we will find several complex issues that are worth studying. My aim is only to paint the general overall picture in order to indicate how I think that the present problems should be approached on a general level.

A. Areas of Tension: The Research Exemption and the Entrepreneurial University

1. The Background

In patent law there has been a classic research exemption or exception. In many European countries it is a statutory restriction on the patentholder's rights, stating that the rights conferred by a patent should not extend to acts done for experimental purposes. A common European formula for this exemption can be found in Article 27 of the European Community patent convention 1989[15], which has impacted patent legislation in many European states, although it never actually has been adopted as a binding EU instrument.[16] According to Article 27 of the EC Community patent convention from 1989, the rights conferred by a Community patent shall not extend to, inter alia,

> (a) acts done privately and for non-commercial purposes; and
> (b) acts done for experimental purposes relating to the subject-matter of the patented invention.

In other countries it is only a traditional accepted fact that the exclusive right of the patent owner covers only commercial use, and

15. Council Directive 89/695/EEC, Agreement Relating to Community Patents, art 27, Dec. 15, 1989, 1989 O.J. (L 401) 1, 30.

16. The reason with this is mainly due to disagreements concerning the language regime and the court system for the EU patent; it is not due to material patent law issues.

experimental use for scientific purposes has been seen as a noncommercial activity. When research has been conducted within universities that maintain a passive role towards patenting and IP, it has been especially easy to justify the research exemption, at least for academic research. It is however important to emphasize that legislation usually does not differ between academic and non-academic research in the regulation of the exemption. The prevailing position is that there is a sphere of use of the invention, which concerns collecting knowledge related to the subject matter of the patented invention and its functions, and that such activities cannot be regarded as infringements. There is however a large grey area about what kind of activities can be conducted based on this exemption. It is therefore not very surprising that there has been an extensive debate in legal literature, as well as court cases and new legislative activities in this field. The changing nature of academic research and academic business relationships has broadened the grey area, and, in this respect, considerable diverging opinions and legislative solutions exist internationally.

The new role of universities – as developing in Europe and explained above – clearly poses a challenge to the IP regime. What should we do with the research exemption? How does current IP law meet the needs of modern research and research institutions?

With this development, the full tension between scientific and commercial goals must be internalized within universities. The issue is no longer making some exceptions from general academic principles for research results that have commercial potential. The special goals of universities and the sphere of openness and public domain within them must be redefined and guaranteed. At the same time, we have to take into account the fact that some of the research done within universities and university policy in this respect make universities a player on the innovation and patent market. Although the core principles of academic research which can be referred to as "public and open" should prevail, IP policy within universities might imply limited restrictions on and exceptions to these principles. In order to make this possible, adaptation of general IP regulation and

internal policies, as well as awareness within academic institutions, is needed. This development clearly has implications for technology in which the patent option is evident, but also for other areas where IP can be claimed.

An example of this is database protection in Europe. Databases are not only protected as works of authorship, but also as *sui generis* rights. This protection applies to databases that show a "qualitatively and/or quantitatively . . . substantial investment in either the obtaining, verification or presentation of the contents." It is clear that claiming of IP for academic databases might hamper research. There is at present no research exemption for use of databases in the European Union. Still, we know that the process of creating new knowledge might be very expensive. European Union database protection does not protect the creator of knowledge. It rewards the investor who assembles the data, not the creator of the data. As the British Royal Society has pointed out in its critical assessment of this legislation, the cost of obtaining these data much exceeds the investment in assembling the database.[17]

From the point of view of the European patent system, the lack of any grace period for patentable inventions becomes a clear problem in an Entrepreneurial University where the possibility for patenting should be borne in mind by researchers and their university at all times. In Europe, the publication of research results clearly will be delayed as a consequence of patent considerations; therefore, expedient processes must be in place in order to select research results that are subject to limitations.

2. *The Research Exemption*

One of the most complicated areas concerning the relationship between universities and patenting is related to the so-called research exemption. It is dealt with in this section.

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17. WORKING GROUP ON INTELLECTUAL PROPERTY, THE ROYAL SOCIETY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE (2003), http://royalsociety.org/displaypagedoc.asp?id=11403 [hereinafter KEEPING SCIENCE OPEN].

At present the research exemption is not directly regulated in any international Patent Treaty with obligatory binding effect.[18] Indirectly it has been argued that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement poses certain limitations to all kind of research exemptions because of the World Trade Organization (WTO) panel's quite strict interpretation[19] of the so-called three steps test, that for patents is codified in Article 30 of TRIPS:

> **Exceptions to rights conferred.** Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[20]

The three steps test indicates that for an exception to comply with the TRIPS Agreement, it must (1) be limited, (2) not unreasonably conflict with the normal exploitation of the patent, and (3) not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. These criteria have been regarded to be cumulative: all three must be met for an exception to be valid in terms of Article 30.

It seems however to be questionable how far conclusions can be drawn from the existing WTO panel's practice. There is no case that has explicitly addressed the issue of research exemptions. Although it

18. As was indicated above, the European Union Patent Treaty CPC has not been finally adopted for ratifications.

19. *See, e.g.*, Chris Dent, Paul Jensen, Sophie Waller & Beth Webster, *Research Use of Patented Knowledge: A Review* 13-16 (OECD Directorate for Science, Technology and Industry (STI), Working Paper 2006/2, 2006), *available at* http://www.oecd.org/dataoecd/15/16/36311146.pdf; *see also* Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY: UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 861-883 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

20. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), *available at* http://www.wto.org/english/tratop_e/TRIPS_e/t_agm0_e.htm.

is true that the panel has had a strict approach to, for instance, what can be regarded as limited exceptions, some panel reasoning has explicitly referred to the research exemption as an example of what is meant by "legitimate interests" in Article 30 of TRIPS.[21] Furthermore, the linkage made by the panels between the application of the three steps test in patent and copyright law might also indicate that comparable extensive research exemptions might be acceptable within the interpretative framework of article 30 of TRIPS.[22]

In European countries we find formulas very much based on the Community Patent Convention (CPC).[23] We also find some new regulations. In Belgium we find new legislative efforts: the renewed Patent Act of April 25, 2005, no longer uses the traditional formula, which stated that the rights conferred by a patent shall not extend to experiments related to the subject matter of the patented invention. Now the Act explicitly states that the rights of a patent holder do not extend to acts carried out for scientific purposes on or with the subject matter of the invention.[24] According to the preparatory works of the new Act, the term "scientific purposes" refers to acts that aim at collecting knowledge and shall be given a broad interpretation. It encompasses both acts with a strict scientific purpose and acts with a mixed scientific/commercial aim, provided that mixed research should be mainly scientific in nature.[25] The new Swiss legislation was presented by the recent Gower report[26] as a good example of a modern research exemption. It reads:

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21. *See* Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, ¶ 7.69, WT/DS114/R (Mar. 17, 2000).

22. Within copyright law, different research exceptions have traditionally been accepted as necessary for cultural, educational, and similar purposes.

23. A good overview of European case law in the late 1990s is given by William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 IIC : INT'L REV. OF INDUS. PROP. & COPYRIGHT L. 735 (1998).

24. Geertrui Van Overwalle,*The Implementation of the Biotechnology Directive in Belgium and its After-Effects: The Introduction of a New Research Exemption and a Compulsory License for Public Health*, 37 IIC: INT'L REV. OF INTELL. PROP. AND COMPETITION L. 889, 906 (2006).

25. *See id.*

26. *See* ANDREW GOWERS, HM TREASURY, REVIEW OF INTELLECTUAL PROPERTY 47 (2006), *available at* http://www.hm-treasury.gov.uk/media/6/E/pbr06_gowers_report_755.pdf (recommending Britain to amend section 60(5) of the Patents Act 1977 to clarify the research exception to facilitate experimentation, innovation, and education).

The effects of a patent do not extend:

> (a) to acts undertaken in the private sphere for non-commercial purposes
>
> (b) to acts undertaken for experimental and research purposes in order to obtain knowledge about the object of the invention, including its possible utilities; in particular all scientific research concerning the object of the invention is permitted
>
> (c) to acts necessary to obtain a market authorization for a medicament according to the law of 15 December 2000 on therapeutic products.
>
> (d) to the use of the invention for the purpose of teaching in teaching establishments
>
> (e) to the use of biological material for the purposes of selection or the discovery and development of a plant variety
>
> (f) to biological material obtained in the field of agriculture which was due to chance or which was technically unavoidable.[27]

On a global scale we find wide divergences in the ways a research exemption is regulated and assessed. We can note that especially the common law countries of Australia, Canada, New Zealand, and the United States do not have any statutory exemption concerning the experimental use of patents. Also in these countries court practice seems to differ. In New Zealand there is relatively recent case law recognizing the experimental use exemption.[28] In New Zealand the government has, however, decided to introduce a research exemption for New Zealand patent legislation. In June 2006, the Cabinet agreed that the infringement provisions of the draft Patents Bill that is pending in New Zealand be amended by the insertion of an experimental use exception.[29]

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27. *Id.* at 46.

28. *See* Dent et al., *supra* note 19, at 20.

29. *See* New Zealand Ministry of Economic Development, Analysis: An Experimental Use Exception for the Patents Act: Analysis of Submissions, June 22, 2006, http://www.med.govt.nz/templates/MultipageDocumentPage____20423.aspx, which presents the decided amendment in the following form:

In the United States, we find the recent remarkable strict ruling of *Madey v. Duke University*.[30] Here the Federal Circuit held that Duke's use of laser technology that had been previously patented by a recently departed researcher constituted patent infringement.[31] In holding for the plaintiff Madey, the court stated that "so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."[32] Duke had argued that it qualified for the experimental use exception because its alleged infringement served no commercial purpose and occurred within the context of non-profit university research. The court, however met this argument with a broad interpretation of the concept of a university's commercial or business interests by stating that the patented laser technology "unmistakably further[s] the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."[33] The logic simply is that because Duke is in the business of teaching and conducting research, use of Madey's patented laser represented a commercial application and therefore constituted patent infringement. This interpretation is very narrow indeed, and it is actually unique in its strictness worldwide. It is therefore not surprising that it has launched a huge

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> The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of the patent.
>
> Acts done for experimental purposes relating to the subject matter of the invention include:
>
> - determining how the invention works;
> - determining the scope of the invention;
> - determining the validity of the claims;
> - seeking an improvement to the invention.

Id.

30. Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).
31. *Id.*
32. *Id.*
33. *Id.*

debate in the United States.[34] Many authors have come up with different proposals on how one could strengthen the research exemption.

B. The Present Problems

Today research is very international; it is conducted in international cooperation. Researchers interact online on a daily basis with each other although they are based in different countries and jurisdictions. Things do not get easier for the researchers if the same patent can be used by researchers involved in academic research in one country but not in another. The problems of today however are not only due to the fact that the regulation might vary from one country to another. There are several other problems.

First, the current regulation is highly unclear. As many authors point out there is a large grey area where no one really can tell what rules apply. The lack of clarity is stated by several international organizations. It is also true for the requirements that the TRIPS Agreement poses on its members concerning patent law.[35]

One important explanation for why the situation is unclear and why court cases after all are quite rare is that in practice there actually exists an "informal" research exception, which is applied especially in countries like the U.S. that have a narrow research exception. Christina Weschler describes this as systematic rational ignorance, utilized by researchers to obtain licenses for technology that can be replicated easily in a laboratory or when technology is available through an unauthorized supplier on terms more favorable

34. *See* JOHN R. THOMAS, CRS REPORT FOR CONGRESS, SCIENTIFIC RESEARCH AND THE EXPERIMENTAL USE PRIVILEGE IN PATENT LAW (2004); Denise W. DeFranco, et. al., *The Experimental Use Exception: Looking Towards a Legislative Alternative,* 6 J. HIGH TECH. L. 93 (2006); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12 (2003); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004); Tom Saunders, Comment, *Renting Space on the Shoulders of Giants:* Madey *and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261 (2003).

35. See Dinwoodie & Dreyfuss, *supra* note 19.

than those offered by the patent holder.[36] As long as such behavior is connected to non-commercial research work, there is no interest on the side of companies to stop these practices. Also, the existing collaborative ties between business and academia might be endangered if companies aggressively pursue infringers that actually have not caused them any considerable economic loss. In certain situations Weschler also has seen that universities and other non-profit organizations are offered very favorable below-market licensing agreements.

In a situation where universities try to raise their income based on patented inventions within the framework of what we have called an Entrepreneurial University, it might be difficult to justify a research exemption, either informal or formal. It is therefore important to introduce criteria for how to handle situations where academic research has different faces or rationales. The conclusion is that the on-going developments are due to changes in the role and functions of IPR in our economies. The strong infiltration of IPR considerations into all academic research is a fact or a reality we cannot avoid.

Furthermore, the situation is becoming more and more complicated. Within the experimental use discussion we handled several different types of experiments and behavior. When looking for solutions, we must take these factors into account.

C. The Possible Solutions

There is no return to the Ivory tower. On the other hand, even the Entrepreneurial University, with commercial interests of its own, is not primarily a market player in the same sense as big private corporate actors. The university still has to take care of its teaching, training, and other research duties.[37] Furthermore, the many roles

36. Cristina Weschler, Note, *The Informal Experimental Use Exception: University Research After* Madey v. Duke University, 79 N.Y.U. L. REV. 1536, 1552 (2004); *see also* Rebecca S. Eisenberg, *Reaching Through the Genome*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT: ADVANCES IN GENETICS 209 (F. Scott Kieff ed., 2003).

37. *See also* Dreyfuss, *supra* note 31, at 468.

played by academia indicate that this complex situation cannot be regulated by simple rules. There are several different types of situations that might be at stake. At least three different situations might be at hand that clearly complicate the debate.

The first one can be characterized as core traditional experimental use, involving experiments on the patented invention for scientific purposes. This kind of use has to be guaranteed in all circumstances and cannot be dependent on any permission by the patent owner. As Cornish puts it:

"The initial inventor of new technology should not be permitted to use his pioneer patent as a check on further experimentation by others into the subject matter of the invention. It must not be for him alone to add to industrial knowledge, free of competitive pressure for continuing improvement and variation. With the arrival of biogenetic techniques in the pharmaceutical laboratories the issue has come to a head. In Germany and Holland it is now accepted that clinical tests with formulations of a patented active substance are generally within the exception. This is because of necessity they will be seeking for further knowledge."[38]

It is more difficult to justify a general experimental use exception for all kinds of *research tools*. Many commentators accept experiments on the invention, but not with it. Also, there has been severe criticism raised against the issuing of patents with broad scope in this area.[39] Furthermore, it is not very clear which criteria should be used when classifying an invention as a research tool in different fields of science, as, for instance, nanotechnology.[40] It does not seem feasible to introduce a general research exemption for all kinds of research tools. Here, different proposals from the U.S. debate might be well suited. One could be allowed to use patented research tools as long as all results of the research are published and not patented. This kind of proposal has been made by Dreyfuss, who has proposed that a university or a non-profit research institution that wants to use

38. Cornish, *supra* note 22.
39. KEEPING SCIENCE OPEN, *supra* note 17, at 10.
40. *See* Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601 (2005).

patented material and cannot obtain a license from the patentee on reasonable terms could use the technology without permission if it is willing to sign a waiver. The waiver would require the institution to promptly publish the results of work conducted with the patented technology and refrain from patenting any inventions made in the course of that work. Another solution could be some kind of compulsory license system or the lack of any sanctions for infringement that does not lead to any commercial results for the infringer.

A third area has to do with experiments on a patented invention that are necessary for putting the product on the market. These situations have to be dealt with separately, as to a large extent is already the case in law and practice. These issues are of special interest for pharmaceutical products and for foodstuff (plant varieties).

CONCLUSION

My final conclusion is that we need international cooperation in order to find a balanced solution for the scope and design of the research exemption. If and when the on-going Substantive Patent Law Treaty (SPLT) negotiations within the World Intellectual Property Organization (WIPO) reaches basic harmonization in patent law, the research exemption should be addressed. Immediately needed, however, is enhanced cooperation between universities and their international organizations in order to come up with some common proposals to achieve basic international rules on experimental use of patents that will guarantee basic academic freedom and at the same time function within the framework of the new Entrepreneurial University. This is only one, but important, challenge of many to adapt the IP regulatory system to the reality of academic teaching and research of today.